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September 24, 1999

Via Federal Express

Ms. Jennie Butler
Dockets Management Branch
Food and Drug Administration
Department of Health & Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 99P-2554/CP

TO WHOM IT MAY CONCERN:

INTRODUCTION

Recently, E. Excel International, Inc. ("E. Excel") learned that Mr. John Buttolph, Esq. purporting to act on behalf of the "Health Product Claims Alert," filed a complaint with the Food and Drug Administration falsely alleging that E. Excel has violated a number of its laws, rules and regulations. With this letter, E. Excel takes the unusual step of voluntarily responding to these allegations (even though the FDA has not requested a response). It does so because E. Excel will aggressively rebut any false, misleading and defamatory allegations about it or its products, particularly when they are found in a public document such as that filed by Mr. Buttolph.

As will be demonstrated herein, E. Excel has violated no laws, and the FDA should take no further action based upon the specious allegations filed by Mr. Buttolph. Should the FDA have any questions or request any further information regarding this matter before summarily dismissing Mr. Buttolph's claims, it can expect E. Excel's full and complete cooperation.

GENERAL RESPONSE

Prior to responding to any specific allegations contained in Mr. Buttolph's complaint, it must be noted that his complaint has not been filed "in the public interest." Instead, it has been filed for the sole purpose of causing competitive injury to E. Excel. Mr. Buttolph is a witting or unwitting dupe of one of E. Excel's most bitter competitors.

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This is most clearly revealed by Mr. Buttolph's references to literature which has never been published by E. Excel, which has never been used by E. Excel in the United States, or which has long since been discontinued. The fact that Mr. Buttolph relies upon these documents shows that the purported interest in the public safety is disingenuous at best.¹

As further proof of Mr. Buttolph's true motive, he engages in what can only be characterized as an attempt to prejudice the reader(s) of his complaint and to smear E. Excel and its founder, Jau-Fei Chen, Ph.D. ("Dr. Chen"). Mr. Buttolph alleges that both Dr. Chen and E. Excel have been involved in prior violations of federal labeling laws, citing an incident regarding the importation of surgical gloves from China. The characterization of that incident is grossly inaccurate.

The true facts are that in the very late 1980's and early 1990's, when the AIDS epidemic was coming to the public forefront, there was a severe shortage of latex surgical gloves in the United States. Dr. Chen took on the task of marketing thousands of these gloves which had initially been imported by or at the suggestion of her brother, Tei Fu Chen. At this time, Dr. Chen was primarily involved with the business of E. Excel and its nutritional products. Accordingly, she relied upon a person who was in her church and whom she hired to properly market those gloves. That person advised Dr. Chen that since the gloves were packaged and marketed in the United States, it was proper to label the boxes as "Manufactured for E. Excel International, Inc., U.S.A."

¹The most clear example of this is Mr. Buttolph's repeated quotations or references to "an E. Excel Product Information" document. See p. 3 of the complaint. That publication, however, has never been published by E. Excel. has never been sold by E. Excel. and has never been endorsed or encouraged by E. Excel. In fact, its publication is strictly prohibited by E. Excel's policies and procedures. Similarly, Mr. Buttolph makes reference to an "E. Excel Promotion Brochure." That document was published in 1994 and at that time was consistent with the practices in the health and nutrition industry. It has long been discontinued, particularly with the passage of the DHSEA.

At page 2 of the complaint is a reference to an "E. Excel International brochure 1999" (as is apparent from the addresses on the brochure). This document is not used by E. Excel in the United States, but is used only in Malaysia, consistent with that country's laws.

At page 4, Mr. Buttolph purports to quote from page 15 of the 1997 *A Profile in Excellence*, but none of the quoted language can be found on that page.

As it turns out, such labeling violated federal law because the labeling should also have noted that the gloves were "manufactured in China." It should be made clear, that there was never any question as to the quality of the gloves or concerns about health or safety. The gloves met all FDA requirements for surgical gloves, including their thickness, sterility, and porosity.

Based upon these facts, the United States entered into a plea bargain agreement wherein Dr. Chen and E. Excel pled guilty to a mere *misdemeanor* violation that required no showing of any specific intent to violate the labeling laws. See Transcript of Hearing and comments of the Hon. J. Thomas Greene at the time of acceptance of the plea bargain, copy attached hereto as Exhibit 1. Again, contrary to the rather, at best, imprecise statements of Mr. Buttolph, E. Excel and Dr. Chen did not plead guilty to any felony, and they were not fined more than \$184,000. In fact, the fine was only \$2,000 for Dr. Chen and \$4,500 for E. Excel.

Mr. Buttolph also alleges that E. Excel has previously violated labeling laws citing an alleged problem with the "True Balance" product which was introduced in 1989, E. Excel's first year of operations. Being new in the industry, E. Excel modeled its initial labels after those of some of its competitors with similar type products. E. Excel is unaware of any claim or contention that E. Excel's labels actually did violate any federal laws, but if they did, then so did those of many other nutritional supplement companies during that period. More importantly, however, Mr. Buttolph fails to mention that sales of the "True Balance" product in the United States was discontinued in 1994.

It is next contended that E. Excel failed to provide its marketing literature to an FDA field inspector in August 1998. With all due respect to Mr. Buttolph, he is simply incorrect. Attached hereto as Exhibit 2 is the FDA Form 484, dated August 19, 1998, which shows that Ms. Jill Mielziner of the FDA received various samples of products and "3 Videotapes for promotion -- 'Nutritional Immunology: A New Science,'" and "3 pamphlets called 'E. Excel's Family Products' 'The Excellent Word' 'E. Excel International, A Profile of Excellence.'" Mr. Buttolph's assertions that E. Excel did not provide literature are simply bogus. E. Excel did provide copies of the marketing literature that it was publishing and using at that time in the United States. The other books, brochures or pamphlets which Mr. Buttolph has cited in his complaint and which he apparently contends should have been produced to Ms. Mielziner, were, in fact, not published by E. Excel, were not used by E. Excel or were not used by E. Excel in the United States.

As can be seen, Mr. Buttolph has a clear propensity to misrepresent the facts. Thus, it is not surprising that he also misquotes and mischaracterizes E. Excel's philosophy and literature. Whether Mr. Buttolph's actions are intentional, reckless or grossly negligent or whether any of Mr. Buttolph's claims should be considered credible will be for the reader to determine after reviewing E. Excel's history and its specific responses to Mr. Buttolph's allegations.

GENERAL BACKGROUND

E. Excel was founded in 1987 and began doing business in 1989 selling nutritional supplements. Its founder is Jau-Fei Chen, Ph.D. Dr. Chen obtained her doctorate degree in Biochemistry in 1988 from Brigham Young University, specializing in Immunology. See letters from Brigham Young University attached hereto as Exhibit 3. In other words, unlike several of her competitors, she has actually earned the title of "Doctor" through a rigorous course of academic study, rather than obtaining that title from mere self-designation or from honorary degrees.

Dr. Chen and E. Excel firmly believe, as does almost any reasonable person, that a person's health can be positively or negatively affected by the nourishment one provides to the body. Studies and the human experience reveal time after time that those who are not properly nourished often suffer from a wide variety of human ailments and certainly become more susceptible to infection and disease. Conversely, well-nourished individuals have stronger immune systems and are able to enjoy healthier lives and repel disease.

This is certainly not a unique concept. It is one shared by many others because it is inherently logical and reasonable. Indeed, the DHSEA itself notes these obvious facts:

Congress finds that--

.....
(2) the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies

.....
(5) preventive health measures, including education, good nutrition, and appropriate use of safe nutritional supplements will limit the incidence of chronic diseases, and reduce long-term health care expenditures;

.....

- (7) there is a growing need for emphasis on the dissemination of information linking nutrition and long-term good health;
 - (8) consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements;
-

E. Excel markets a complete line of herbal food products. Contrary to Mr. Buttolph's allegations, in none of the literature which has been produced (and particularly none so since the enactment of the DHSEA) does E. Excel make any claim that its products will cure or treat any disease or ailment. What it does claim is that people will be healthier by eating the E. Excel food products. It does claim that there is a vast body of knowledge about herbs -- scientific, empirical, observational, and anecdotal which backs the claims that certain herbs can support, nourish and strengthen the body as a whole as well as specific bodily systems.

Dr. Chen has devoted substantial time investigating, researching, collaborating with other others, and developing nutritional supplements that are believed to support the body and the immune system. She has termed this study and concept as "Nutritional Immunology". That is all that Nutritional Immunology is, a term coined by Dr. Chen to describe her study of the effects of specific foods on the immune system to help people avoid and resist disease rather than cure or treat it. With this concept in mind, E. Excel will now respond to a number of the more significant allegations in Mr. Buttolph's complaint regarding mislabelling, improper claims, and lack of substantiation.

SPECIFIC RESPONSES

1. Claims of mislabelling.

Contrary to what Mr. Buttolph alleges, nowhere does E. Excel ever suggest that "[Dr. Chen] asserts that the only source of the proper foods that can nourish the immune system properly are from her company." Complaint, p.2, para. 3. Mr. Buttolph cites page 45 of *Plant Foods & Immunology: A Scientific Approach* in support of this quote, but that page is entirely devoid of any such claims, either expressly or impliedly.

It is next alleged that E. Excel's 'Phytocopia' and "Nutriall" products lack the required labels. E. Excel discontinued marketing its Phytocopia product in 1997 prior to

the time that the new labelling laws became mandantory on March 23, 1999.² With respect to "Nutriall," since at least March 23, 1999, E. Excel attached stickers with the "Nutrition Facts" to its existing supply of boxes for Nutriall, and the new boxes have the Nutrition Facts imprinted on them. A copy of the sticker that has been attached to the Nutriall box is attached hereto as Exhibit 4.

2. Allegations that E. Excel makes improper medical claims.

Beginning at page four of his complaint, Mr. Buttolph attempts to construct a case that E. Excel is making unsubstantiated drug claims that the E. Excel products will cure diseases. He constructs his arguments on a foundation of sand. The bases for his arguments are:

1. A book authored by Jau-Fei Chen entitled Plant Foods & Immunology: A Scientific Approach. Mr. Buttolph ignores the fact that this book, which contains substantial scientific evidence of the link between nutrition and effects upon the immune system, makes no mention of E. Excel or any of its products. Such a publication was contemplated and addressed in Section 403B of the DHSEA (21 U.S.C. § 343-2) which clearly recognizes that books regarding herbs can be sold if they do not mention specific products.

2. An E. Excel publication entitled The Excellent Word. Mr. Buttolph attempts to paint a false and misleading picture by failing to quote extensive language in that publication which places the snippets cited by Mr. Buttolph into proper context.

3. Materials regarding E. Excel's long discontinued product "Phytocopia."

4. A document entitled E. Excel Product Information. Although Mr. Buttolph literally devotes pages of his complaint to quotations from this document, he fails to inform the reader that this document was not authored by E. Excel, not sold by E. Excel and not endorsed by E. Excel.³

² As Mr. Buttolph knows (or should know) the nutrition statements currently required by the DHSEA were not required on dietary supplements until March 23, 1999. See Federal Register attached hereto as Exhibit 5.

³ Since receipt of Mr. Buttolph's complaint, E. Excel has been attempting to discover the sources of that document. It appears to originally have been created by an

Since the bulk of Mr. Buttolph's "evidence" is based upon documents not published by E. Excel or published by E. Excel prior to the enactment of the DHSEA, only those specific references to literature published by E. Excel will be addressed. The first of these are quotations from The Excellent Word. Admittedly, that brochure describes some of the exciting research being performed worldwide which studies the effects of certain herbs and foods upon certain illnesses. What Mr. Buttolph fails to do, however, is to quote the extensive language in that document which explains to E. Excel's distributors why that information is provided to them:

The information contained within this publication is included for reference and educational purposes only. It is not intended as a substitute for the advice of a qualified medical professional. E. Excel products are herbal food supplements designed to nourish the body's immune system and/or to support the health of specific bodily systems through regular use. The E. Excel products are not for the treatment or cure of any diseases, illnesses or ailments. E. Excel International, Inc. does not condone or advocate self-diagnosis or self-medication in any way. If you have a condition which requires medical diagnosis and treatment, it is important that you visit a licensed health professional.

This publication may also contain references to scientific research that has been performed regarding one or more herbs used in the E. Excel products. These articles have been referenced in order to demonstrate that the scientific community is documenting and verifying the amazing and wonderful powers of specific herbs, but under the specific circumstances and uses described in the referenced studies. Because the E. Excel product formulations contain different combinations of herbs, different amounts of herbs, and may use the herbs differently than those described in any referenced articles or studies, the use of E. Excel products will not achieve the same specific results described in the cited articles. No claim is made by E. Excel that since its products contain herbs described in the studies, that the regular use of its products will achieve the

independent distributor in Taiwan who was terminated after E. Excel discovered the publication of that document. The version apparently in Mr. Buttolph's hands appears to be an English translation of most of that document. E. Excel intends to take aggressive action to ensure that E. Excel distributors do not use the rogue and unauthorized E. Excel Product Information.

specific results described in the studies. Any such claim made by any person is specifically disavowed and disclaimed by the Company.

Page 3. (Emphasis added.)

As can be seen, Mr. Buttolph's repeated references to the research studies cited in the E. Excel literature has been taken grossly out-of-context. As stated at the beginning of the publication (and as quoted above), E. Excel does not claim that its products cure diseases or illnesses.

Strangely, Mr. Buttolph also fails to cite other language in E. Excel's publications which clearly and properly make the distinction between (1) the use of herbs to support, nourish and strengthen bodily systems to avoid disease and (2) the use of herbs to cure or treat diseases. For instance, attached hereto as Exhibit 6 are copies of E. Excel's other promotional materials. The first document, simply entitled: "E. Excel international" makes the following statements:

"If poor health can so easily devastate your dreams, just imagine how a body protected from sickness could change your life. You would have more energy, more time, and more enthusiasm to chase your ambitions. You would be on the path of better health leading you to more fulfilling rewards. Simply put, you could enjoy life just a little bit more, and feel great doing it."

"Your body is equipped with a powerful immune system, a defense mechanism which can be strengthened and improved through proper nourishment and care However, if it [the immune system] is denied the most essential nutrients, it becomes weak and inefficient, leaving the body vulnerable to attack

This relationship between nutrition and the performance of the immune system is the key to improved health. In fact, this special science of building the immune system on a day-to-day basis with proper fuel is called *nutritional immunology*

Simply put, nutritional immunology is the study of these and similar effects of plant foods on the functioning of the immune system. This science is the answer to poor health."

"Dr Chen hopes to teach others how to prevent - rather than treat - illness and disease through a properly nourished immune system."

"The whole-food formulations are the best available, and E. Excel continues to create wonderful products for the improvement of health and nutrition

"E. Excel's greatest goal is to help people build stronger immune systems and improve their quality of life. Our whole-food products are designed for this very purpose, offering optimal nutrition for the body in a convenient and delicious form."

"But if the body is to perform its duties properly, it must be supplied with healthy, nutritious foods derived from plants.

In recent years, it has become apparent that a diet rich in phytochemicals holds great potential for protecting the human body against illness and disease

It is our belief that eating right is more than a way of life; it is an investment toward living a long and healthy life."

"Balanced nutrition is an invaluable weapon in fortifying the body's own defenses."

"The information contained within this publication is included for reference and educational purposes only. It is not intended as a substitute for the advice of a qualified medical professional. E. Excel International, Inc. does not condone or advocate self-diagnosis or self-medication in any way. If you have condition which requires medical diagnosis and treatment, it is important that you visit a licensed health professional." (Emphasis added.)

E. Excel's clear distinction between promoting general health and prevention rather than curing or treating specific diseases is not a recent development. It has been found consistently through its literature, particularly since the passage of the DHSEA. For example, in A Profile in Excellence,⁴ 1997, pp. 15-16, E. Excel states:

Dr. Chen decided there was a better way to address the problem of poor health than searching for cures. She drew upon the tradition of herbal use that stems from her Chinese heritage and combined it with her extensive immunological research to create the science of Nutritional Immunology as a way to help people achieve and maintain good health by

⁴ It should be noted that A Profile of Excellence is a publication which simply describes the many accomplishments of Dr. Chen. None of E. Excel's products are even mentioned in this publication.

preventing – rather than treating – disease through a properly nourished immune system. The immune system's very purpose is to protect the body from disease and illness, and when functioning properly, it has all the ammunition it needs to ward off disease, combat illness and even overcome the constant attacks of environmental pollutants and toxins

There are definite links between nutrition and how well the immune system functions, and these links are the basis of Nutritional Immunology – the special science of strengthening the immune system on a day-to-day basis

Plant foods such as fruits, vegetables, and herbs provide much of the nutrition that the body needs. Scientific research has also confirmed that plants contain phytochemicals which can actually inhibit cancer and other diseases in mammals. In addition to inhibiting cancerous cells, phytochemicals are also believed to prevent dietary fat from promoting tumors, reduce the probability of colon, breast, and prostate cancer, reduce the growth of microorganisms, and improve blood lipids and serum cholesterol levels. The science of Nutritional Immunology, founded by Dr. Chen, examines such effects of plant foods on the functioning of the human immune system.

Mr. Buttolph's allegations regarding improper medical claims simply cannot withstand critical examination. E. Excel does not make improper claims about its products. It is responsible in the promotion of its products and in full compliance with the DHSEA.

3. Nutritional Support Claims.

In a desperate "shotgun" effort to find any fault with E. Excel, Mr. Buttolph next alleges that E. Excel has failed to comply with labeling requirements by omitting language required by 21 U.S.C. § 343(r)(6)(C). Again, this allegation is without merit. 21 U.S.C. § 343(r) provides that if claims are made in the labeling of the product, then the following disclaimer must also appear on the label: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

This provision is wholly inapplicable because none of the labels on the E. Excel products make any health claims of any type.

4. Substantiation

In his final parting shot, Mr. Buttolph insinuates that somehow E. Excel acted improperly by not providing information to Ms. Mielziner of this agency. He states: "This is especially alarming since the chart [from the E. Excel Product Information booklet] referenced in the preceding section and many of the claims mentioned in this Citizen Petition were taken from promotional material delivered by E. Excel this past week to my organization." With all due respect, Mr. Buttolph is a liar. E. Excel does not publish or distribute the E. Excel Product Information booklet anymore. Further, attached hereto as Exhibit 7 is a true and complete copy of the invoice/packing statement showing those materials provided to Mr. Buttolph when he ordered product from E. Excel on or about July 16, 1999. As can be seen, he ordered no brochures describing the products or promotional literature, only the food products themselves.⁵

Further, as discussed previously, E. Excel did provide its then-current video and marketing literature to Ms. Mielziner. It did not provide copies of brochures which it did not author or promote, and it did not provide copies of documents used in foreign countries.

⁵ Through its own investigation, E. Excel has learned that one of its independent distributors apparently supplied some of the unauthorized information to Mr. Buttolph. That distributor has advised E. Excel that she has not distributed the E. Excel Product Information booklet for a "very long time" and that she only sent it and some other information because Mr. Buttolph was so insistent on getting additional information about E. Excel. That distributor also has provided E. Excel a copy of the E. Excel Product Information booklet, representative pages of which are attached hereto as Exhibit 8. The bottom of those pages state: "The information contained within this material is included for reference and educational purposes only. It is not intended as a substitute for the advice of a qualified medical professional. E. Excel International does not endorse or advocate self-diagnosis or self-medication in any way. If you have a condition which requires medical diagnosis and treatment, it is important that you visit a licensed health professional. The opinions expressed by authors and contributing distributors do not necessarily reflect the opinions of E. Excel International", and "This data is for information only. It has been collected from various sources and is historical in nature. It is not intended to take the place of advice from a physician. This data is not produced by E. Excel International - nor is it distributed by them." (Emphasis added.)

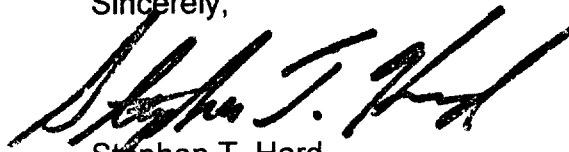
Ms. Jennie Butler
Food and Drug Administration
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With respect to the mere assertions that E. Excel did not have "substantiation" for its claims, it would behoove Mr. Buttolph to explain what "claims" he thinks E. Excel has made in its literature (as opposed to the unauthorized and unendorsed literature of others). If there are any such "claims," E. Excel has no doubt that it will be able to back those up in full compliance with the DHSEA.

CONCLUSION

Based upon the foregoing, E. Excel respectfully requests the FDA to summarily reject the complaint as being groundless. Any further questions regarding this matter should be directed to the undersigned.

Sincerely,



Stephen T. Hard